Fast-Track Regulation
Agency Background Document

Agency name	Board of Medicine, Department of Health Professions
Virginia Administrative Code (VAC) citation(s)	18VAC85-50-10 et seq.
Regulation title(s)	Regulations Governing the Practice of Physician Assistants
Action title	Amendment to requirement for physician signature on the PA prescription
Date this document prepared	7/13/2015

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Orders 17 (2014) and 58 (1999), and the *Virginia Register Form, Style, and Procedure Manual.*

Brief summary

Please provide a brief summary (preferably no more than 2 or 3 paragraphs) of the proposed new regulation, proposed amendments to the existing regulation, or the regulation proposed to be repealed. Alert the reader to all substantive matters or changes. If applicable, generally describe the existing regulation.

The amended regulation will eliminate the requirement for the signature of the supervising physician on a prescription written by a physician assistant if the assistant is writing a prescription for a Schedule VI drug. Amendments in subsection B will clarify how the physician assistant can comply with the disclosure requirement specified in § 54.1-2952.1 of the Code of Virginia.

Acronyms and Definitions

Please define all acronyms used in the Agency Background Document. Also, please define any technical terms that are used in the document that are not also defined in the "Definition" section of the regulations.

N/A

Statement of final agency action

Please provide a statement of the final action taken by the agency including:1) the date the action was taken; 2) the name of the agency taking the action; and 3) the title of the regulation.

On June 18, 2015, the Board of Medicine adopted an amendment to 18VACC85-50-10 et seq., Regulations Governing the Practice of Physician Assistants.

Legal basis

Please identify the state and/or federal legal authority to promulgate this proposed regulation, including: 1) the most relevant citations to the Code of Virginia or General Assembly chapter number(s), if applicable; and 2) promulgating entity, i.e., agency, board, or person. Your citation should include a specific provision authorizing the promulgating entity to regulate this specific subject or program, as well as a reference to the agency/board/person's overall regulatory authority.

Regulations are promulgated under the general authority of Chapter 24 of Title 54.1 of the Code of Virginia. Section 54.1-2400 (6), which provides the Board of Medicine the authority to promulgate regulations to administer the regulatory system:

> ***§ 54.1-2400 -General powers and duties of health regulatory boards***
> *The general powers and duties of health regulatory boards shall be:*
>
> *6. To promulgate regulations in accordance with the Administrative Process Act (§ 9-6.14:1 et seq.) which are reasonable and necessary to administer effectively the regulatory system. Such regulations shall not conflict with the purposes and intent of this chapter or of Chapter 1 (§ 54.1-100 et seq.) and Chapter 25 (§ 54.1-2500 et seq.) of this title. ...*

The specific legal authority to prescriptive authority for physician assistants is found in:

§ 54.1-2952.1. Prescription of certain controlled substances and devices by licensed physician assistant.
A. In accordance with the provisions of this section and pursuant to the requirements of Chapter 33 (§ 54.1-3300 et seq.) of this title, a licensed physician assistant shall have the authority to prescribe controlled substances and devices as set forth in Chapter 34 (§ 54.1-3400 et seq.) of this title as follows: (i) Schedules V and VI controlled substances on and after July 1, 2001, (ii) Schedules IV through VI controlled substances on and after January 1, 2003, (iii) Schedule III through VI controlled substances on and after July 1, 2004, and (iv) Schedules II through VI controlled substances on and after July 1, 2007.

A licensed physician assistant shall have such prescriptive authority upon the provision to the Board of Medicine of such evidence as it may require that the assistant has entered into and is, at the time of writing a prescription, a party to a written agreement with a licensed physician or podiatrist which provides for the direction and supervision by such licensee of the prescriptive practices of the assistant. Such written agreements shall include the controlled substances the physician assistant is or is not authorized to prescribe and may restrict such prescriptive authority as deemed appropriate by the physician or podiatrist providing direction and supervision.

B. It shall be unlawful for the assistant to prescribe controlled substances or devices pursuant to this section unless such prescription is authorized by the written agreement between the licensee and the assistant.

C. The Board of Medicine, in consultation with the Board of Pharmacy, shall promulgate such regulations governing the prescriptive authority of physician assistants as are deemed reasonable and necessary to ensure an appropriate standard of care for patients.
The regulations promulgated pursuant to this section ***shall include, at a minimum****, (i) such requirements as may be necessary to ensure continued physician assistant competency that may include continuing education, testing, and/or any other requirement, and shall address the need to promote ethical practice, an appropriate standard of care, patient safety, the use of new pharmaceuticals, and appropriate communication with patients; (ii) requirements for periodic site visits by supervising licensees who supervise and direct assistants who provide services at a location other than where the licensee regularly practices; and (iii)* ***a requirement that the assistant disclose to his patients the name, address and telephone number of the supervising licensee and that he is a physician assistant****. A separate office for the assistant shall not be established.*

D. This section shall not prohibit a licensed physician assistant from administering controlled substances in compliance with the definition of "administer" in § 54.1-3401 or from receiving and dispensing manufacturers' professional samples of controlled substances in compliance with the provisions of this section.

Purpose

Please explain the need for the new or amended regulation. Describe the rationale or justification of the proposed regulatory action. Describe the specific reasons the regulation is essential to protect the health, safety or welfare of citizens. Discuss the goals of the proposal and the problems the proposal is intended to solve.

The purpose of the amendment is to modify a regulation that is considered burdensome by physician assistants. Facilitating prescribing practice by physician assistants, under the supervision of a physician, will enhance efficiency and access to patient care. Since disclosures about the supervising physician and the licensure of the physician assistant remain in regulation, the amendment to the regulation in subsection A will not lessen protection for the health and safety of the patient.

Rationale for using fast-track process

Please explain the rationale for using the fast-track process in promulgating this regulation. Why do you expect this rulemaking to be noncontroversial?

There is no controversy in the adoption of this amendment; it is recommended by physician assistants and the supervising physicians with whom they work.

Substance

Please briefly identify and explain the new substantive provisions, the substantive changes to existing sections, or both. A more detailed discussion is provided in the "Detail of changes" section below.

The amended regulation will eliminate the requirement for the signature of the supervising physician on a prescription written by a physician assistant if the assistant is writing a prescription for a Schedule VI drug. The physician's name on the prescription will continue to be required if the assistant is writing a prescription in Schedule II through V. Amendments in subsection B will clarify how the physician assistant can comply with the disclosure requirement specified in § 54.1-2952.1 of the Code of Virginia.

Issues

Please identify the issues associated with the proposed regulatory action, including: 1) the primary advantages and disadvantages to the public, such as individual private citizens or businesses, of implementing the new or amended provisions; 2) the primary advantages and disadvantages to the agency or the Commonwealth; and 3) other pertinent matters of interest to the regulated community, government officials, and the public. If there are no disadvantages to the public or the Commonwealth, please indicate.

1) The primary advantage to the public is facilitation of prescribing by physician assistants for greater efficiency and access. There are no disadvantages.
2) There are no advantages or disadvantages to the agency or the Commonwealth.
3) There are no other pertinent matters of interest to the regulated community, government officials, and the public.

Requirements more restrictive than federal

Please identify and describe any requirement of the proposal which is more restrictive than applicable federal requirements. Include a rationale for the need for the more restrictive requirements. If there are no applicable federal requirements or no requirements that exceed applicable federal requirements, include a statement to that effect.

There are no applicable federal requirements.

Localities particularly affected

Please identify any locality particularly affected by the proposed regulation. Locality particularly affected means any locality which bears any identified disproportionate material impact which would not be experienced by other localities.

There are no localities particularly affected.

Regulatory flexibility analysis

Pursuant to § 2.2-4007.1B of the Code of Virginia, please describe the agency's analysis of alternative regulatory methods, consistent with health, safety, environmental, and economic welfare, that will accomplish the objectives of applicable law while minimizing the adverse impact on small business. Alternative regulatory methods include, at a minimum: 1) the establishment of less stringent compliance or reporting requirements; 2) the establishment of less stringent schedules or deadlines for compliance or reporting requirements; 3) the consolidation or simplification of compliance or reporting requirements; 4) the establishment of performance standards for small businesses to replace design or operational standards required in the proposed regulation; and 5) the exemption of small businesses from all or any part of the requirements contained in the proposed regulation.

There are no alternative regulatory methods that will accomplish the objective.

Economic impact

Please identify the anticipated economic impact of the proposed new regulations or amendments to the existing regulation. When describing a particular economic impact, please specify which new requirement or change in requirement creates the anticipated economic impact.

Projected cost to the state to implement and enforce the proposed regulation, including: **a) fund source / fund detail; and** **b) a delineation of one-time versus on-going expenditures**	There is no cost for implementation or enforcement. The amendment will eliminate a requirement that is burdensome in physician practices and will facilitate the use of e-prescribing.
Projected cost of the new regulations or changes to existing regulations on localities.	There are no costs to localities.
Description of the individuals, businesses, or other entities likely to be affected by the new regulations or changes to existing regulations.	The individuals affected will be physician assistants and supervising physicians.
Agency's best estimate of the number of such entities that will be affected. Please include an estimate of the number of small businesses affected. Small business means a business entity, including its affiliates, that: a) is independently owned and operated and; b) employs fewer than 500 full-time employees or	There are 3058 persons who hold a current Virginia license as a physician assistant. Each of those may have multiple supervising physicians. There is no estimate of the number of small businesses because physician assistants do not practice independently and work in many types of practices and employment settings.

has gross annual sales of less than $6 million.	
All projected costs of the new regulations or changes to existing regulations for affected individuals, businesses, or other entities. Please be specific and include all costs including: **a) the projected reporting, recordkeeping, and other administrative costs required for compliance by small businesses; and** **b) specify any costs related to the development of real estate for commercial or residential purposes that are a consequence of the proposed regulatory changes or new regulations.**	There are no costs; the current regulation will increase efficiency and therefore, reduce costs.
Beneficial impact the regulation is designed to produce.	Greater efficiency and facilitation of e-prescribing.

Alternatives

Please describe any viable alternatives to the proposal considered and the rationale used by the agency to select the least burdensome or intrusive alternative that meets the essential purpose of the action. Also, include discussion of less intrusive or less costly alternatives for small businesses, as defined in § 2.2-4007.1 of the Code of Virginia, of achieving the purpose of the regulation.

At its meeting in February of 2015, the full board considered a recommendation from the Advisory Board on Physician Assistants to eliminate the requirement to have the name of the supervising physician on a prescription written by a physician assistant.

A motion was passed to table the recommendation and address it at the June meeting in order to determine whether there were some limitations on having both names appear on an e-prescription.

The matter was discussed at the meeting of the Advisory Board on June 4, 2015. It was reported that Carillion, for example, uses EPIC and the form only includes a place for the physician's name if the assistant is writing a prescription for a Schedule II through V drugs. The members believe there are other examples in other health systems.

Subsequently, the Board agreed that the physician's name was not necessary for a Schedule VI drug, and the amendment would facilitate utilization of e-prescribing within health care systems.

Public participation notice

If an objection to the use of the fast-track process is received within the 30-day public comment period from 10 or more persons, any member of the applicable standing committee of either house of the General Assembly or of the Joint Commission on Administrative Rules, the agency shall: 1) file notice of the objections with the Registrar of Regulations for publication in the

Virginia Register; and 2) proceed with the normal promulgation process with the initial publication of the fast-track regulation serving as the Notice of Intended Regulatory Action.

Family impact

Please assess the impact of this regulatory action on the institution of the family and family stability including to what extent the regulatory action will: 1) strengthen or erode the authority and rights of parents in the education, nurturing, and supervision of their children; 2) encourage or discourage economic self-sufficiency, self-pride, and the assumption of responsibility for oneself, one's spouse, and one's children and/or elderly parents; 3) strengthen or erode the marital commitment; and 4) increase or decrease disposable family income.

There is no impact on the family.

Detail of changes

Please list all changes that are being proposed and the consequences of the proposed changes; explain the new requirements and what they mean rather than merely quoting the proposed text of the regulation. If the proposed regulation is a new chapter, describe the intent of the language and the expected impact. Please describe the difference between existing regulation(s) and/or agency practice(s) and what is being proposed in this regulatory action.

Current section number	Current requirement	Proposed change, intent, rationale, and likely impact of proposed requirements
160	18VAC85-50-160. Disclosure. A. Each prescription shall bear the name of the supervising physician and of the physician assistant. B. The physician assistant shall disclose to the patient that he is a licensed physician assistant, and also the name, address and telephone number of the supervising physician. Such disclosure may be included on the prescription pad or may be given in writing to the patient.	The proposed amendment will amend subsection A, so the name of the supervising physician will not be required in addition to the name of the physician assistant if the assistant is writing for a Schedule VI drug. It will continue to be required for drugs in Schedules II through V. *Physician assistants have requested the change because writing electronic prescriptions has made it difficult to comply, since some pharmacy systems provide no place for a physician's name unless it is a Schedule II – V prescription. Virginia law and regulation requires disclosure and a practice agreement in which the supervising physician specifies the prescriptive authority of the assistant. The regulation has become increasingly burdensome and serves no purpose in terms of patient protection unless there is a scheduled drug involved.* The amendments to subsection B clarify how disclosure of information about a supervising physician must occur – either on the prescription itself or in writing to the patient which could be

		given in the initial contact with the patient. *A regulation for disclosure is required by law, so there is no option. Currently, the regulation seems to imply that disclosure is optional.*